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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/578,254	02/05/2007	Susumu Yamaguchi	4600-0120PUS1	6745

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BIRCH STEWART KOLASCH & BIRCH
PO BOX 747
FALLS CHURCH, VA 22040-0747

EXAMINER

WILLIAMS, LELA

ART UNIT	PAPER NUMBER
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1789

NOTIFICATION DATE	DELIVERY MODE
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01/24/2012

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailroom@bskb.com

Office Action Summary	Application No. 10/578,254	Applicant(s) YAMAGUCHI ET AL.	
	Examiner LELA S. WILLIAMS	Art Unit 1789	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 April 2011.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on ____; the restriction requirement and election have been incorporated into this action.
- 4) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 5) ☒ Claim(s) 26-31 is/are pending in the application.
- 5a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 6) ☐ Claim(s) ____ is/are allowed.
- 7) ☒ Claim(s) 26-31 is/are rejected.
- 8) ☐ Claim(s) ____ is/are objected to.
- 9) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 10) ☐ The specification is objected to by the Examiner.
- 11) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 12) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____. |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>4/21/2011</u> . | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on April 21, 2011 has been entered.

Claim Rejections - 35 USC § 103

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

3. Claims 26-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kyle US 5,550,156.

4. **Regarding claims 26, 27, and 29-30** Kyle discloses blending microbial oils, to include those containing arachidonic acid, with vegetable oil (col. 2, lines 40-65; col. 4, lines 1-5). Kyle teaches the vegetable oil to be borage and black currant seed oil (col. 3, lines 38-50), the same oils identified by Applicant as the preferred oil of the present invention. Therefore, it is clear that the oil intrinsically does not substantially contain alpha-linolenic acid, therefore having an amount of 5% or less, and contains the presently claimed amount of 20-86% oleic acid. The reference does not disclose a definite amount of arachidonic acid to be added to the vegetable oil; however, the reference does disclose:

An objective in mixing the oils is to obtain an additive which will provide an infant formula with a desired omega-3 and omega-6 PUFA composition similar to that found in breast milk. **While the proportion of the desired fatty acids in a microbial oil can vary, this proportion can easily be determined and the amount of oil adjusted to**

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provide the desired amount of PUFA. Similarly, the percentage of desired PUFA in fish oil or vegetable oils can easily be determined and the amount of the oil to be added can be adjusted as necessary to achieve the desired results. (col. 3, lines 20-30)

The reference further teaches:

Typically, human breast milk contain from about 0.5 to 0.6% of its fatty acid content as ARA (col. 6, line 47).

Given Kyle's teaching of breast milk comprising 0.5 to 0.6% ARA, as well as the teaching that the oils were mixed to obtain additive that provides infant formula with similar PUFA composition to that of breast milk, it therefore would have been obvious to one of ordinary skill in the art to add and amount of ARA to vegetable oil in efforts to obtain a final product with at least 0.5 to 0.6% ARA in the final oil product. Further, Kyle states the oils are blended to produce a composition useful in dietary, pharmaceutical or cosmetic purposes (col. 2, lines 50-55) and that one of ordinary skill in the art would have been able to determine approximate amounts of the fatty acid without undue experimentation (col. 6, line 55). Therefore, it was obvious that one of ordinary skill would have determined a suitable amount of ARA needed in the vegetable oil composition, included amounts as presently claimed.

Further, given that Kyle discloses method identical to that claimed, i.e., combining ARA and vegetable oil, it is clear that the ARA would intrinsically improve the body taste of the vegetable oil composition. Furthermore, the limitation of claim 26 that the vegetable fat and oil has an alpha-linolenic acid content of 5% or less is in the preamble which does not limit the claim because the body of the claim following the preamble is self-contained and does not depend on the preamble for completeness.

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Further, regarding the “consisting of language” of claims 29 and 30, given that Kyle taught that a microbial oil containing ARA was blended with vegetable oils such as borage oil and black current seed oil (col. 2, line 50; col. 3, lines 15-20, 38-45, col. 7, lines 25-35) and the reference does not state anything else in the oils, the reference meets the "consisting of" language of the present claims.

Regarding claims 28 and 31, Kyle teaches the arachidonic acid is derived from a microorganism (col. 4, lines 1-5).

Response to Arguments

5. Applicant’s amendment filed on April 21, 2011, is sufficient to overcome the claim objection set forth in the prior Office Action. The objection is withdrawn.

6. Applicant’s amendment filed on April 21, 2011, is sufficient to overcome the 35 U.S.C. 112, first paragraph rejection set forth in the prior Office Action. The rejection is withdrawn.

7. Applicant's arguments filed April 21, 2011 have been fully considered but they are not persuasive.

Applicant argues, “Kyle does not disclose any other vegetable fat and oil which has the recited limited alpha-linoleic acid content.” (page 4) However, the reference recites vegetable oils to include black currant seed oil (*Ribes nigrum*) and borage oil, oils which applicant as identified in the specification, page 11, line 10-25, as preferable since they do not substantially contain alpha-linoleic, but contains 20-86% of oleic acid. Therefore, given Kyle’s explicit disclosure of black currant seed oil (*Ribes nigrum*) and borage oil, one of ordinary skill in the art would have been motivated to utilize said oils. Although applicant argues the reason one would

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attempt to limit the alpha-linoleic acid content in vegetable oil, said argument is unpersuasive given the disclosure of oils which inherently contain said limits.

Applicant also argues “based on Kyle, one of skill in the art would not add ARA to borage oil” because of its GLA content; however Kyle states that “any combination of GLA- EPA- ARA- or DHA-containing oils, with or without fish oil, can be used. The source of the GLA can be a vegetable oil, such as primrose, black currant or borage oil” (col. 7, lines 25-30). Thereby, Kyle clearly teaches a combination of the oils and acid.

Applicant argues on page 5 that Kyle teaches away from the present invention since the reference the addition of DHA; however there is nothing in Kyle which state DHA must be present, in fact, as stated above the reference states, “any combination of GLA- EPA- ARA- or DHA-containing oils, with or without fish oil, can be used.” (col. 7, line 28). Furthermore, applicant's open claim language, i.e., "comprising" does not exclude the addition of DHA.

Regarding applicants statements pertaining to the amount of ARA, applicant states that the range of ARA disclosed in Kyle are from 17.52% to 24.75%, however, these are only amounts taken from a few examples of the reference. The reference as a whole does not state a specific amount of ARA added, only stating the amount present in the final product (col. 6, line 47) and that the amounts can vary and are easily determinable by one of ordinary skill in the art (col. 3, lines 20-30 and col.. 6, line 55). Therefore, it would have been within the skill level of one of ordinary skill to determine a suitable amount of ARA needed in the vegetable oil composition, included amounts as presently claimed, dependent on the purpose (dietary, pharmaceutical or cosmetic) of the final product.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LELA S. WILLIAMS whose telephone number is (571)270-1126. The examiner can normally be reached on Monday to Thursday from 7:30am-5pm (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Humera Sheikh can be reached on 571-272-0604. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/LELA S WILLIAMS/
Examiner, Art Unit 1789